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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No. S940150

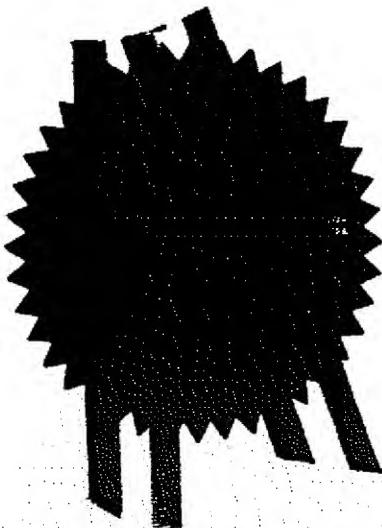
Date of filing 18 February, 1994

Applicants GAYA LIMITED, an Irish Company of
43 Fitzwilliam Place, Dublin 2,
Republic of Ireland.

Dated this 28th day of February, 1995

V. Cunningham

An officer authorised by the
Controller of Patents, Designs and Trade Marks.



Request for the Grant of a Patent

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

- the grant of a patent under Part II of the Act
 the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder

1. **Applicant(s)**

Name : GAYA LIMITED

Address : 43, Fitzwilliam Place, Dublin 2, Republic of Ireland.

Description/Nationality : A company organised under the laws
of the Republic of Ireland.

2. **Title of Invention** ACCESS PORT

3. **Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)**

Previous filing date

Country in or for which filed

Filing No.

4. **Identification of Inventor(s)**

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

Address

5. Statement of right to be granted a patent (Section 17(2) (b))**6. Items accompanying this Request - tick as appropriate**

- (i) prescribed filing fee (£ 55,00)
- (ii) specification containing a description and claims
 - specification containing a description only
 - drawings referred to in description or claims
- (iii) An abstract
- (iv) Copy of previous application(s) whose priority is claimed
- (v) Translation of previous application whose priority is claimed
- (vi) Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No.: Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

MACLACHLAN & DONALDSON, 47 Merrion Square, Dublin 2

9. Address for Service (if different from that at 8)

MACLACHLAN & DONALDSON, at their address as recorded for the time being in the Register of Patent Agents (Rule 92)

Signed Name(s): GAYA LIMITED

By: *Marie Walsh*

MACLACHLAN & DONALDSON, Applicants Agents

Capacity (if applicant is a body corporate):

Date 18th February 1994

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APPLICATION No.....

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ACCESS PORT

The present invention relates to an access port for use in surgery and particularly for use in minimally invasive 5 surgery i.e. surgery carried out by causing the minimum amount of trauma by incision in a patient's body.

A sleeve for use in minimally invasive surgery forms the subject matter of a co-pending patent application. The 10 purpose of this prior art sleeve is to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. For surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the purpose of the sleeve is to 15 prevent gas escaping from the patient's body cavity while allowing the surgeon to operate using minimally invasive surgery techniques. The patent application proposes a sleeve having a flange provided with adhesive for adhering the device to the patient's body or alternatively having a 20 mounting ring surrounding the incision in a patient's body.

However, the prior art device suffers from the disadvantage, inter alia, that in use, the sleeve protrudes upwardly from the patient and may interfere with the 25 activities of the surgery team.

The prior art device also suffers from the disadvantage that the sleeve includes a sealing means to seal the sleeve against the surgeon's upper forearm. This results in a 30 restriction of the blood supply to the surgeon's fingers because of the constriction on the upper forearm. Furthermore, when a surgeon is operating on an infected area, for instance, when removing cancerous tissue, there is a real risk that as he withdraws his gloved hand or an 35 instrument from the location in the patient's body cavity

in which he is operating, his glove may rub against the tissue immediately surrounding the incision, thereby spreading the cancerous cells to that location.

- 5 The present invention seeks to alleviate the disadvantages associated with the prior art sleeve.

The present invention accordingly provides an access port device for use in surgery comprising a sleeve having an entry opening located at a proximal end of the sleeve and an exit opening located at a distal end thereof for insertion into an incision made in a patient's body, the exit opening allowing access to the patient's body cavity, and entry sealing means for sealing the entry opening, whereby when the patient's body cavity is inflated by gas, the entry sealing means prevents substantial leakage of gas from the patient's body cavity while providing access for digits of a hand and/or hand itself and sealing about portion of the arm remaining outside the access port device.

Advantageously, the entry sealing means comprises an inflatable chamber provided on the proximal end of the sleeve. The inflatable chamber may be inflated using a separate valve from that used to inflate the patient's body cavity. When the access port is in use, fluid communication is possible between the inflated chamber and the patient's body cavity so as to equalise the pressure in the inflated chamber and in the body cavity.

30 Preferably, the sleeve is provided with a flange having adhesive thereon for adhering the access port to the patient's body. Advantageously, the flange is located at the proximal end of the sleeve so that when the flange is 35 adhered to the patient's body, the distal end of the sleeve

is inserted through the incision and is inside the patient's body cavity and the access port projects a short distance above the patient's body.

- 5 When the distal end of the sleeve is inserted through the incision, the patient's muscle tissue around the incision may act as a sealing means for assisting in sealing the intermediate portion of the sleeve between the distal end and the proximal end.

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The present invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, one embodiment of an access port in accordance with the invention.

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Figure 1 is a perspective view of the access port device from above showing the proximal end of the sleeve uppermost;

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Figure 2 is also a perspective view of the access port from above, with a portion thereof not shown, for clarity;

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Figure 3 is a perspective view of the access port from underneath.

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Referring to the drawings, the access port is indicated generally by reference numeral 1 and comprises a sleeve 2 having a proximal end 3 and a distal end 4. The proximal end 3 of the sleeve 2 comprises a flange 5 and an inflatable chamber 6 having a entry opening (mouth) 7 through which a surgeon's hand may enter.

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For surgery, an incision is made in the body of the patient, such an incision being made preferably along the

muscle rather than across the muscle of the patient.

In order to assist in securely affixing the access port 1 to the patient's body, an adhesive sterile wrapping material may be adhered to the patient's body and an

- 5 incision can made through the wrapping material. The distal end 4 of the sleeve 2 is inserted into the incision and is pushed into the body cavity of the patient (which is not inflated at this stage) until the flange 5 contacts the wrapping material or the patient's skin, as the case may be
- 10 if adhesive wrapping material is not used. The adhesive flange 5 is then adhered to the wrapping material or the skin as the case may be, thereby securely affixing the access port 1 to the patient. The action of the muscle tissue around the incision causes the muscle tissue to
- 15 press against the sleeve 2.

In order to seal the entry opening 7, gas is pumped into the inflatable chamber 6 causing it to inflate and thereby seal the entry opening 7. The patient's body cavity is

- 20 then inflated. The gas used to inflate the inflatable chamber 7 may be pumped into the chamber 7 via a different valve from that used to inflate the patient's body cavity.

- Since fluid communication between the inflated chamber 6 and the patient's body cavity is possible when the access port 1 is in use, the pressure within the inflated chamber 6 is the same as the pressure within the patient's body cavity.

- 30 When the surgeon desires to insert his gloved hand through the access port, he pushes his gloved hand through the entry opening 7 and down through the sleeve 2. As a surgeon forces his arm through the entry opening 7, the now inflated chamber 6 seals against his forearm. Since the
- 35 seal is formed about a larger surface area on the surgeon's

- forearm that was the case in the prior art, the blood supply to the surgeon's finger tips does not become restricted. The surgeon pushes his gloved hand through the incision made in the patient and the action of the muscle tissue at the incision site has the effect of gripping the sleeve 2 and sealing it against the surgeon's forearm. Therefore, there are two seals in operation, namely, one seal which forms around the surgeon's forearm due to the action of muscle tissue at the incision site pressing and sealing the sleeve 2 against the surgeon's forearm and a second seal at the entry opening 7 of the access port 1 where the inflated chamber 6 seals about and against the surgeon's upper forearm.
- 15 When it is desired for the surgeon to withdrawn his hand out of the access port 1 of the invention, as the surgeon's withdraws his hand, the muscle tissue around the incision site clamp in on the sleeve 2 creating a seal against the sleeve 2 and as the surgeon withdraws his hand from the entry opening 7, the seal is maintained.

A further advantage of the access port 1 of the present invention is that manipulation of the access port of the present invention can be carried out using one hand. The prior art device required two hands in order for the surgeon to remove his "operating" hand out of the sleeve. Furthermore, because the distal end 4 of the sleeve 2 is inside the patient's body cavity, as the surgeon retracts his gloved hand, if his glove rubs against the side of the sleeve 2, the incision site does not come into contact with any infected tissue which might be carried upwardly from the operation site on the surgeon's hand or instrument.

It will be understood that the size of the access port can 35 be varied to accommodate, for instance only one finger

rather than the entire hand and arm of the surgeon and also
may accommodate instruments. It is envisaged that it will
be possible for the surgeon to take an instrument down
through the sleeve while carrying the instrument in
5 his hand.

The access port device may be manufactured from any
flexible, gas impermeable, sterilisable, biocompatible
material, for instance polyethylene.

10 It will of course be understood that the invention is not
limited to the specific details described herein, which are
given by way of example only, and that various
modifications and alterations are possible within the scope
15 of the invention as defined in the appended claims.

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CLAIMS

1. An access port device for use in surgery comprising a sleeve having an entry opening located at a proximal end of the sleeve and an exit opening located at a distal end thereof for insertion into an incision made in a patient's body, the exit opening allowing access to the patient's body cavity, and entry sealing means for sealing the entry opening, whereby when the patient's body cavity is inflated by gas, the entry sealing means prevents substantial leakage of gas from the patient's body cavity while providing access for digits of a hand and/or hand itself and sealing about portion of the arm remaining outside the access port device.
- 15 2. An access port as claimed in claim 1, wherein the sealing means comprises an inflatable chamber provided on the proximal end of the sleeve.
- 20 3. An access port as claimed in claim 1 or 2, wherein the sleeve is provided with a flange having adhesive thereon for affixing the access port to the patient.
- 25 4. An access port as claimed in claim 3, wherein the flange is located at the proximal end of the sleeve so that when the flange is adhered to the patient's body, the distal end of the sleeve is inserted through the incision and is inside the patient's body cavity and the access port projects a short distance above the patient's body.

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5. An access port substantially in accordance with any one
of the preceding claims, with reference to and as shown
in the accompanying drawings.

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Applicants' Agents,
47 Merrion Square,
DUBLIN 2.

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A B S T R A C T

ACCESS PORT

- 5 An access port (1) for use in surgery comprising a sleeve (2) having an entry opening (7) located at a proximal end (3) of the sleeve (2) and an exit opening (8) located at a distal end (4) thereof. In use, the distal end (4) of the sleeve (2) is inserted in an incision made in a patient's
10 body and the exit opening (8) allows access to the patient's body cavity. The access port also includes sealing means (6) for the entry opening (7) which comprises an inflatable chamber (6). In use, the muscle tissue around the incision acts as a sealing means for assisting
15 in sealing the sleeve (2) at the distal end (4). The access port (1) enables creation of a controlled environment within the sleeve.

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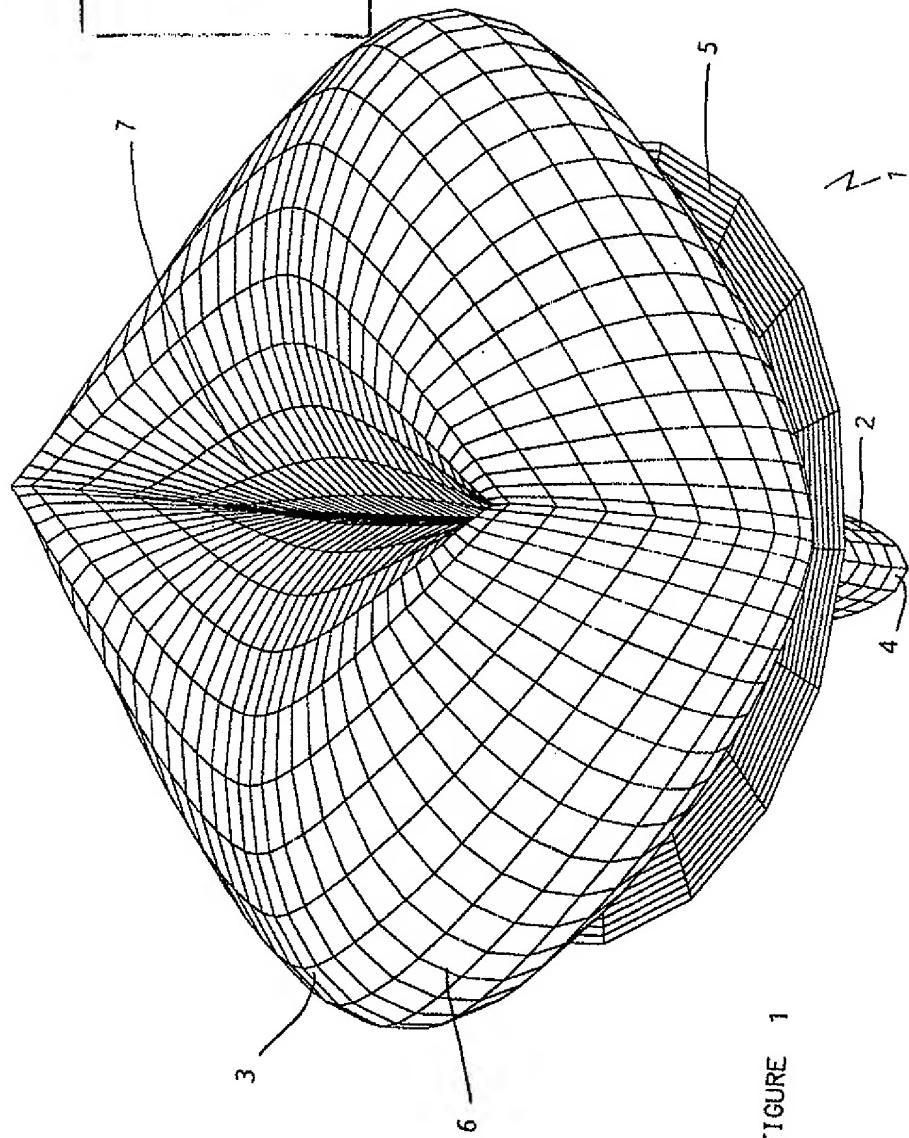


FIGURE 1

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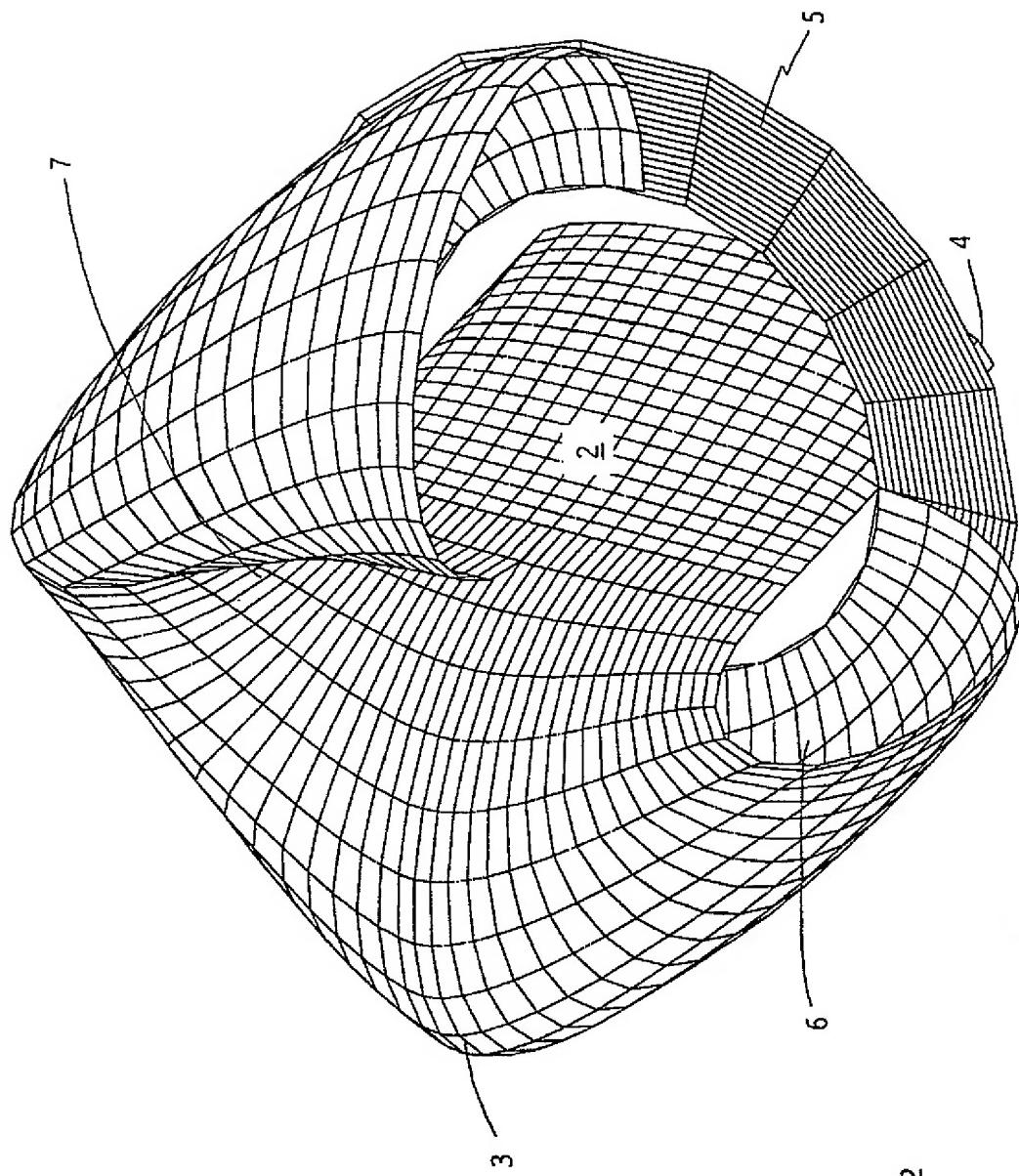


FIGURE 2

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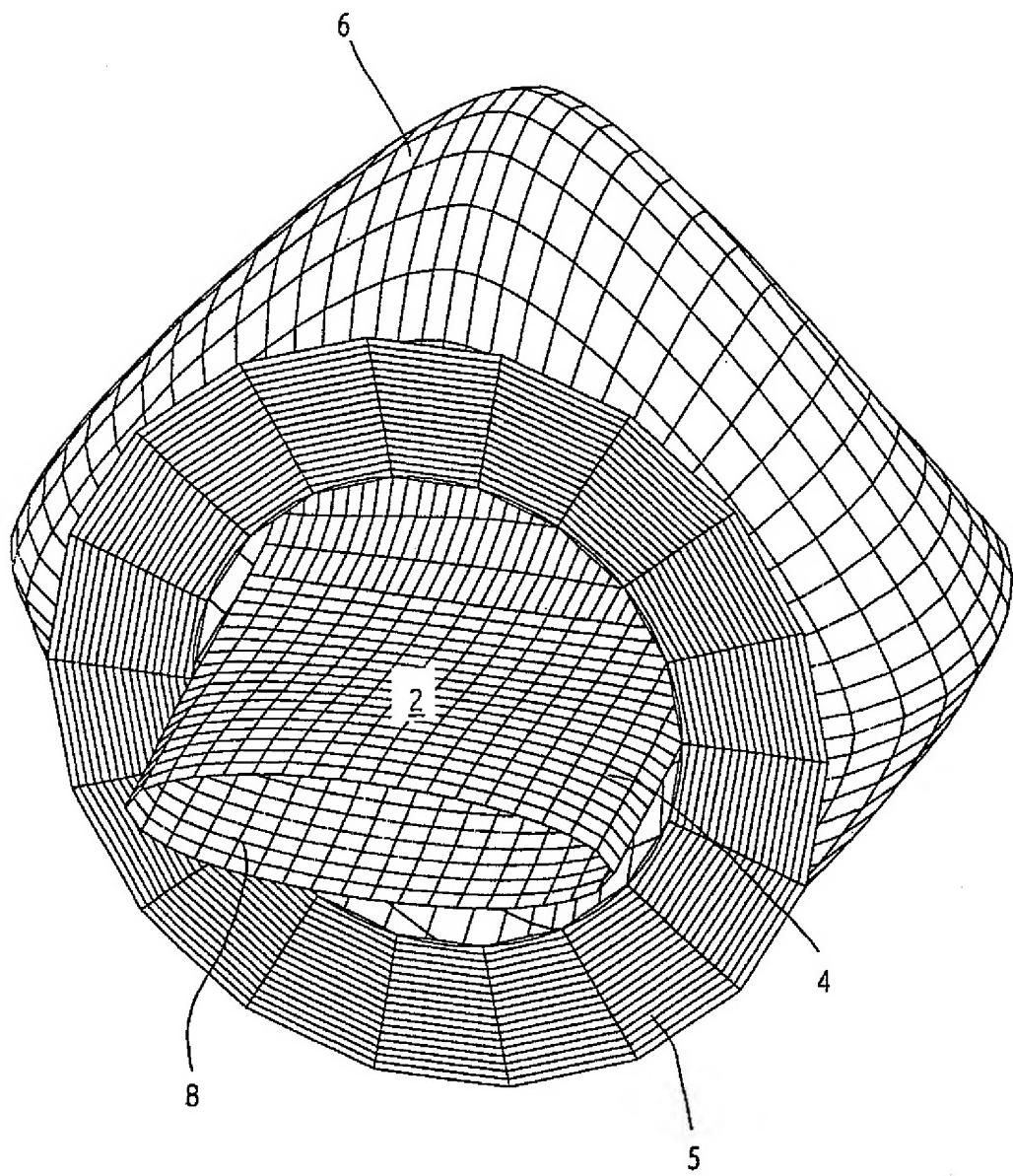


FIGURE 3

